

Amendment and Response

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Serial No.: 10/620,548

Confirmation No.: 8448

Filed: 16 July 2003

For: DELIVERY OF HYDROGEL COMPOSITIONS AS A FINE MIST**Remarks**

The Office Action mailed 27 September 2006 has been received and reviewed. Claims 1, 4, 14, 18, 19, and 30 having been amended, and claims 22, 25, and 34 having been canceled herein, the pending claims are claims 1, 4-15, 18-21, 23-24, and 26-33.

Claims 1 and 14 have been amended to correct obvious typographical and/or grammatical errors.

Independent claim 4 has been amended to move a recitation from the preamble to the body of the claim. Claim 4 (as amended) recites, in the body of the claim, that "the dental composition is capable of being sprayed as a fine mist into the oral environment."

Independent claims 18, 19, and 30 have been amended to recite that "the composition is in the form of a fine mist." The amendments are supported, for example, by dependent claims 22, 25, and 34, respectively (all now canceled).

Reconsideration and withdrawal of the rejections are respectfully requested.

Rejections under 35 U.S.C. §102

The Examiner rejected claims 1, 4-15, and 18-34 under 35 U.S.C. §102(e) as being anticipated by Rennie et al. (U.S. Patent Publication No. 2004/0033260). Claims 22, 25, and 34 having been canceled, the rejection as applied to pending claims 1, 4-15, 18-21, 23-24, and 26-33 is respectfully traversed.

The present application claims priority to application Serial No. 10/001,251, filed 1 November 2001.

To support the rejection under 35 U.S.C. §102(e), the Examiner relied on the disclosure in Rennie et al. of "Lutrol F-127" as a "thermoreversible polymer" (page 2 of the Office Action mailed 27 September 2006), specifically pointing in Rennie et al. to paragraphs [0072] and [0091] (i.e., Table II). Rennie et al. is a continuation-in-part of U.S. Serial No. 09/692,634, filed on 9 October 2000, an image of which is available on the public Patent Application Information Retrieval (PAIR) database. Because Applicants' Representatives could not locate any support for

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either "Lutrol F-127" or a "thermoreversible polymer" in U.S. Serial No. 09/692,634, Applicants respectfully submit that the 102(e) date for the disclosure of Rennie et al. relied upon by the Examiner to support the present rejection is 6 June 2003, the filing date of Rennie et al. (U.S. Serial No. 10/456,465). For at least the reason that the 102(e) date of Rennie et al. (i.e., 6 June 2003) is subsequent to the priority date of the present application (1 November 2001), Applicants respectfully submit that Rennie et al. is not available as art against the present application under 35 U.S.C. §102(e). Thus, Applicants respectfully submit that the rejection is moot.

The Examiner rejected claims 18, 19, and 30 under 35 U.S.C. §102(b) as being anticipated by Kramaric et al. (EP 0 551 626 A1). This rejection is respectfully traversed.

Independent claims 18, 19, and 30 have been amended to incorporate the language of dependent claims 22, 25, and 34, respectively (all now canceled). Applicants respectfully submit that Kramaric et al. do not anticipate claims 18, 19, and 30 (as amended) for at least the reasons that Kramaric et al. did not anticipate dependent claims 22, 25, and 34 (all now canceled).

Reconsideration and withdrawal of the rejections under 35 U.S.C. §102 are respectfully requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1, 4-15, 20-29, and 31-34 under 35 U.S.C. §103(a) as being unpatentable over Kramaric et al. in view of Hill et al. (U.S. Patent No. 4,950,479). Claims 22, 25, and 34 having been canceled, the rejection as applied to pending claims 1, 4-15, 20-21, 23-24, 26-29, and 31-33 is respectfully traversed.

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally,

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the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure."

M.P.E.P. §2143.

The Present Claims

In one aspect, the present claims provide spray devices (e.g., independent claims 1, 14, 15, and 26) that include an aqueous dental composition. Each spray device is capable of *spraying* a dental composition as *a fine mist* into the oral environment.

In another aspect, the present claims provide dental compositions (e.g., independent claims 4, 18, 19, and 30) that include, among other things, a thermally responsive viscosity modifier and water. Each dental composition is capable of being *sprayed* as *a fine mist* into the oral environment (e.g., independent claim 4) or is in the form of *a fine mist* (e.g., independent claims 18, 19, and 30).

Notably, the present specification recites that "a 'fine mist' or 'aerosol' means fine droplets of a liquid sprayed into the air or, alternatively, a gaseous suspension of a fine liquid and/or colloidal particles" (page 5, lines 8-10).

As further discussed herein below, Applicants respectfully submit that neither Kramaric et al. nor Hill et al., either alone or in combination, teach or suggest a dental composition in the form of a fine mist or capable of being *sprayed* as *a fine mist* into the oral environment. Further, Applicants respectfully submit that neither Kramaric et al. nor Hill et al., either alone or in combination, teach or suggest a spray device capable of *spraying* a dental composition as *a fine mist* into the oral environment.

Kramaric et al.

Kramaric et al. "belongs to the field of pharmaceutical industry and relates to a novel stable and improved thermoreversible gel as a liquid pharmaceutical carrier for a galenic

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formulation for application of active substances onto skin, eye or mucous membranes of body cavities" (page 3, lines 4-6). The Examiner noted that Kramaric et al. "differs from the instant claims in its silence regarding administration via spray/aerosol devices, or composition containing propellants" (page 5 of the Office Action mailed 27 September 2006). Kramaric et al. further recite applying galenic forms "in the sol form or by spraying" (page 8, lines 23-24) "onto a damaged skin as a result of burns, mechanical lesions etc." (page 8, lines 22-23). However, because spraying can encompass, for example, spraying a stream of liquid, Applicants respectfully submit that "spraying" is neither an explicit nor implicit disclosure of "spraying as a fine mist." Finally, Kramaric et al. fail to disclose or suggest *spraying dental compositions into the oral environment*, much less dental compositions in the form of *a fine mist* or sprayed as *a fine mist* into the oral environment.

Hill et al.

Hill et al. recite "a method for interrupting plaque formation comprising periodically introducing in the oral hygiene cavity an efficacious [*sic*] composition in the form of a dentifrice spray, measured drops, masticatable capsules, liquid centered chewing gums and the like" (abstract). The Examiner noted that Hill et al. "*does not specify thermoreversible compositions*" (page 6, lines 6-7 of the Office Action mailed 27 September 2006; emphasis added). For at least this reason, Applicants respectfully submit that one of skill in the art, absent the present disclosure, would have no motivation to modify the teachings of Kramaric et al. by Hill et al.

Further, as noted herein above, Hill et al. provide no explicit disclosure or suggestion of any dental composition in the form of *a fine mist* or sprayed as *a fine mist* into the oral environment. Specifically, Applicants note that Hill et al. provide the following recitation:

The spray pattern of the compositions of the present invention can be adjusted to optimize the perceived benefits of mouth, feel, etc. For example, an aerosol spray tends to be more broken up and discharged with greater force than that obtained with a pump spray. In

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certain preparations of the present invention, *the aerosol spray is overwhelming and not a pleasant experience.*
(Column 8, lines 51-58; emphasis added).

Thus, Hill et al. teach that an aerosol spray may not be desirable for the oral environment. Further, to the extent that the "aerosol spray" recited by Hill et al. might arguably inherently include spraying as a fine mist, Applicants respectfully submit that the teaching in Hill et al. that an aerosol spray may not be desirable for the oral environment is, in fact, a teaching away from the presently claimed invention.

"[A] reference that 'teaches away' from a given combination may negate a motivation to modify the prior art to meet the claimed invention. . . . A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Ormco Corp. v. Align Technology Inc.*, 79 U.S.P.Q.2d 1931, 1938 (Fed. Cir. 2006).

Applicants respectfully submit that for at least this reason that Hill et al. teach that an aerosol spray may not be desirable for the oral environment, the Examiner's proposed motivation to modify Kramaric et al. by Hill et al. has been negated by teachings of Hill et al.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

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Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of January, 2007, at 11:09 a.m. (Central Time).

By: Name: Rachel Augliardi